REMARKS

Applicants have withdrawn their appeal by filing the accompanying Continued Prosecution Application. Claims 1-25 are pending with claims 21-25 added by this paper. Support for these claims can be found in the claims as originally filed at page 5, lines 24-29, and Examples 1-4 at page 11, line 13 - page 13, line 27.

Claim Rejections Under 35 USC §102(b)

Applicants respectfully submit that there is no anticipation because both the Virtanen and Olinger patents relate to granulating xylitol, not dissolving the xylitol in a solvent.

In the Examiner's Answer, the Office asserted that the rejected claims are product-by-process claims, and patentability is based on the product and not its method of production.

However, even if the prior art and rationale provided by the Examiner appears to show that the claimed product is allegedly the same or similar to that of the prior art, although produced by a different process, then only the burden shifts to applicant to come forward with evidence establishing an unobvious (or novel) difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) and M.P.E.P. 2113.

Attached hereto is a declaration where the declarant attests to the differences between spraying a sorbitol solution onto a xylitol bed (relevant to Virtanen and Olinger) and co-spraying a xylitol-sorbitol solution onto a xylitol-sorbitol bed (relevant to the present invention). These experiments were carried out as described by Example 2 of Virtanen in order to prepare powders containing 97% of xylitol and 3% sorbitol. Moreover, the experiments were carried out using a SHUGI granulator.

As depicted in the attached scanning electron microscopy pictures, powders TG27/1 and TG28/1 (relevant to Virtanen and Olinger) depict particles with a needle structure. In marked contrast, powder TG31/1 (relevant to the present invention) does not show this needle structure. Rather, the surface of powder TG31/1 is composed of a mixture of sorbitol and xylitol. Consequently, the spraying techniques relevant to Virtanen and Olinger result in different structural properties of powder particles as compared to spraying techniques of the present invention. Also, the experiments demonstrate that introducing sorbitol solution and xylitol to a granulator does not form a homogeneous solution prior to granulation. Therefore, Applicants

respectfully submit that this declaration provides more than sufficient evidence to establish the unobvious and novel differences between the claimed product and the prior art product. Thus, the Examiner has more than ample legal authority to withdraw these rejections (See Interview Summary of November 7, 2001).

Moreover, the cited references in the Action support the contention that the granulates of Virtanen and Olinger are inhomogeneous. Particularly, Virtanen discloses:

> The granulation process is fundamentally different from the dry mixing of two polyols such as xylitol and sorbitol, such as that disclosed by G. B. Patent Nos. 1,526,020. **The granulation process results in the crystallization of some of the sorbitol or present onto the surface of the xylitol particles forming fine, needle like protrusions.** These needle like protrusions can be seen by electron microscopes, and a photograph showing the granulate of the present invention (with xylitol present in an amount of about 97% by weight, and sorbitol present in an amount of about 3% by weight) is shown in FIG. 1; the needle like crystals can be clearly seen. It is thought that the needle like protrusions are, or at least contribute to, the compressibility of the granulate of the present invention. Blends of xylitol and sorbitol in the proportion covered by the present invention which are simply admixed do not exhibit adequate compressibility and do not exhibit the needle like protrusions in electron micrographs such as those seen in FIG. 1.

Column 7, line 61, - column 8, line 11, emphasis added.

Thus, granulating forms sorbitol needle like protrusions on xylitol particles (an inhomogeneous composition) versus dissolving the xylitol in a solvent, which creates a homogenous composition. Thus, Applicants respectfully submit that there is more than sufficient evidence in the record to demonstrate the patentability (both novelty and unobviousness) of Applicants' invention, and these prior art rejections should be withdrawn.

In addition, claims 10 and 11 (and newly added claims 22, 23 and 25) are process and method claims, which are not subject to the rules governing product-by-process claims. Thus, all the features of these claims should be afforded full patentable weight.

Furthermore, as discussed in further detail below, producing an aqueous solution of xylitol and at least one other polyol, with the resulting mixture having a xylitol content of more

than 90% by weight based on the total polyol content is not taught or suggested by the cited references. Thus, these claims are clearly patentable over the cited art.

Allegedly Anticipated by Virtanen

Virtanen discloses a compressible granulate comprising about 94% to about 98% by weight of xylitol, about 1% to about 5% by weight of a polyol other than xylitol, and less than about 1% by weight of water (column 5, lines 38-42). The granulate is made, preferably, by granulating the ground xylitol with a small amount of sorbitol syrup to crystallize some of the sorbitol onto the xylitol particle surface (column 7, lines 21-25 and lines 61-63).

However, to anticipate a claim, the reference must teach every element of the claim. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) and M.P.E.P. §2131.

Virtanen fails to teach a tabletting aid produced by dissolving the xylitol in a solvent. Rather, Virtanen granulates xylitol crystals. As discussed in Virtanen, the granulation process involves agglomerating crystalline xylitol (ground or otherwise comminuted to a small particle size) by means of polyol based syrup (column 6, lines 25-29). Thus, a granulation process involves the mixing of two or more ingredients in a solid state and leads to inhomogeneous granules. In marked contrast, the tabletting aid of the present invention is produced by dissolving the xylitol in a solvent forming a homogeneous solution. Evaporating the solvent by spray drying or fluidized bed granulation leads to a homogenous tabletting aid.

In the Examiner's Answer, Final Action and during the November 7, 2001 interview, reference is made to Example 2 of Virtanen wherein xylitol powder is allegedly mixed with a sorbitol syrup solution to apparently make a solution. But at column 8, lines 42-44 of Example 2 states:

> A xylitol powder produced according to Example 1 and a 40% by weight sorbitol syrup solution (containing 34% by weight of sorbitol, and less than 5.7% of other polyols) **were introduced** into a granulator (Schugi, manufacturer Schugi, BV, Lelystad, Holland) at a speed of 800 kg/hour (powder) and 50 l/hour (syrup solution) at a temperature of 60 °C.

Column 8, lines 41-46, emphasis added.

Example 2 does not disclose mixing xylitol powder and a sorbitol syrup solution, but rather introducing both into a granulator. Virtanen does not disclose introducing both xylitol powder and sorbitol syrup as a single stream. In fact, this introduction can occur by introducing the xylitol powder and the sorbitol syrup separately into the granulator. Thus, the Example 2 (and the rest of the Virtanen reference) does not disclose forming a solution of xylitol powder and a sorbitol syrup solution. Moreover, there is no indication that the solution obtained is spray dried or "fluidized bed" granulated. Instead the sorbitol solution is said to be sent into a granulator. The resultant grains are then dried in a fluidized bed dryer. This technique is distinct from that claimed by Applicants and does not show or suggest the advantage of spray drying a solution of xylitol and another polyol or the advantage of treating such a solution to fluidized bed granulation.

Thus, there is no anticipation of the claimed invention.

Allegedly Anticipated by Olinger

Olinger discloses a directly compressible, non-cariogenic xylitol granulate which comprises xylitol and a binder in the range of about 0.1% to about 5% by weight, wherein the binder is physiologically acceptable, non-cariogenic and is taken from the group consisting of polymerized reducing sugars, alkali carboxymethylcellulose and hydrogenated starch hydrolysate (column 5, line 65 to column 6, line 4). In one method, an aqueous binder solution is added to milled xylitol, and the resulting granulate is dried and screened. (Column 7, lines 8-10). Thus, Olinger adds a solution to the granulate, but does not dissolve the granulate. Olinger also discloses a directly compressible granulate comprising a polyol such as mannitol, lactitol, sorbitol, isomalt and maltitol or a sweetener suitable for diabetic applications such as crystalline fructose and/or mixtures thereof, and a polydextrose binder present in the range of about 0.1% to about 5% by weight. (Column 7, lines 16-22).

However, to anticipate a claim, the reference must teach every element of the claim. See *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) and M.P.E.P. §2131.

As discussed above for Virtanen, granulating is not the same as dissolving the xylitol in a solvent and spray drying or fluidized bed granulation. Olinger fails to teach a tabletting aid

produced by dissolving the xylitol in a solvent. Thus, there is no anticipation of the claimed invention.

Claims 1-20 stand rejected as allegedly obvious by Virtanen in view of U.S. Patent No. 5,958,471 (Schwarz) and U.S. Patent No. 5,576,014 (Mizumoto).

Claim Rejections Under 35 USC §103

In the Examiner's Answer, the Office states that Schwarz is relied upon solely for the teaching of an effective drying temperature of between 120°C and 300°C (Applicants assume that the Office is asserting this reference against claims 3 and 10, although these claims define spraying the mixture in a stream of air at 120° to 300°C). The Office also alleges that Mizumoto is relied upon solely for the teaching of antacid and analgesic agents in a compress molding products (Applicants assume that the Office is asserting this reference against claim 14). If so, Applicants respectfully submit that these rejections should be withdrawn with respect to the remaining claims, at least as merely being duplicative with, for example, the independent claim. Nonetheless, these references cannot render the present invention obvious as discussed below.

No desirability to support alleged combination

Virtanen, as discussed above, granulates xylitol crystals. Schwarz relates, at least in part, to compositions obtainable by dissolving at least two polyols in water (column 2, lines 7-8). Virtanen fails to teach the desirability of dissolving the xylitol crystals in a solvent for, after subsequent processing, creating a tabletting aid. The mere fact that references can be combined or modified does not render the resultant combination *prima facie* obvious unless the prior art also suggests the desirability of the combination. See *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990), M.P.E.P. §2143.01. Here, Virtanen's requirement that crystals of xylitol contain a surface coating of crystals of another polyol teaches against forming a homogenous solution of xylitol and polyol prior to crystallizing. Thus, there is no motivation to combine these references. Further demonstrating the lack of motivation to combine these references, Schwarz broadly defines the suitable range of "between 50:50 and 99:1" for compositions of sorbitol and xylitol at col. 2, lines 13-15. This ratio is inconsistent with the proportions required by Virtanen, namely 94% -98% xylitol (column 5, lines 38-43). There is no teaching or suggestion to modify the composition proportions of Schwarz to

make them compatible with Virtanen. Lacking this teaching, there is no motivation to support this combination of references.

Moreover, Mizumoto fails to cure the deficiencies in the Virtanen reference because Mizumoto's dissolving compressed molding is also made by mixing or granulating various components, *see e.g* column 7, lines 19-46. Consequently, there is no *prima facie* case of obviousness.

Significant and Unexpected Results

Supererogatorily, the present invention exhibits significant and unexpected results. A *prima facie* case of obviousness based on similarity is rebuttable by proof that the claimed invention possesses unexpectedly advantageous or superior properties. See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and M.P.E.P. §2144.09.

The Action of September 12, 2000, and the Examiner's Answer allege that there is no criticality in the amount of a particular component, *e.g.* xylitol, because the prior art obtains the same results desired by Appellant, *i.e.* a direct compressed tablet. This Action also alleges that the amount has not been shown to provide any unusual and/or unexpected results over the applied prior art.

Appellant traverses these allegations. As discussed in the present specification, comparative example 2, pure xylitol, even spray dried, does not possess the required tabletting properties. Rather, the addition of up to 10%, preferably 5-10%, of a second polyol, preferably mannitol, can achieve the desired results (see, e.g. Examples 1-4). Consequently, Applicants respectfully submit that the present invention exhibits significant and unexpected results, at least due, in part, to the disclosure in the present specification.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which can be expedited by a telephone conference, the Examiner is courteously invited to telephone Counsel at the number indicated below.

Respectfully submitted,

James E. Ruland (Reg. No. 37,432)
Attorney/Agent for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

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